INDONESIA MEDICAL DEVICES REGULATORY UPDATE 2018

Ministry of Health
Directorate General of Pharmaceutical and Medical Device
Directorate of Medical Device and Household Health Product Evaluation

Presented on 23rd AHWP, KL Malaysia

GOALS OF MD REGULATORY SYSTEM IN INDONESIA

Ensure the safety, quality, performance / efficacy, affordable and appropriate Medical Devices

Facilitating medical device technology innovation into Indonesia

CURRENT PHASE OF MEDICAL DEVICE REGULATORY

Regulate MD since 1991

Strives to simplify regulations:

Faster review timeline

Easy acces for license application

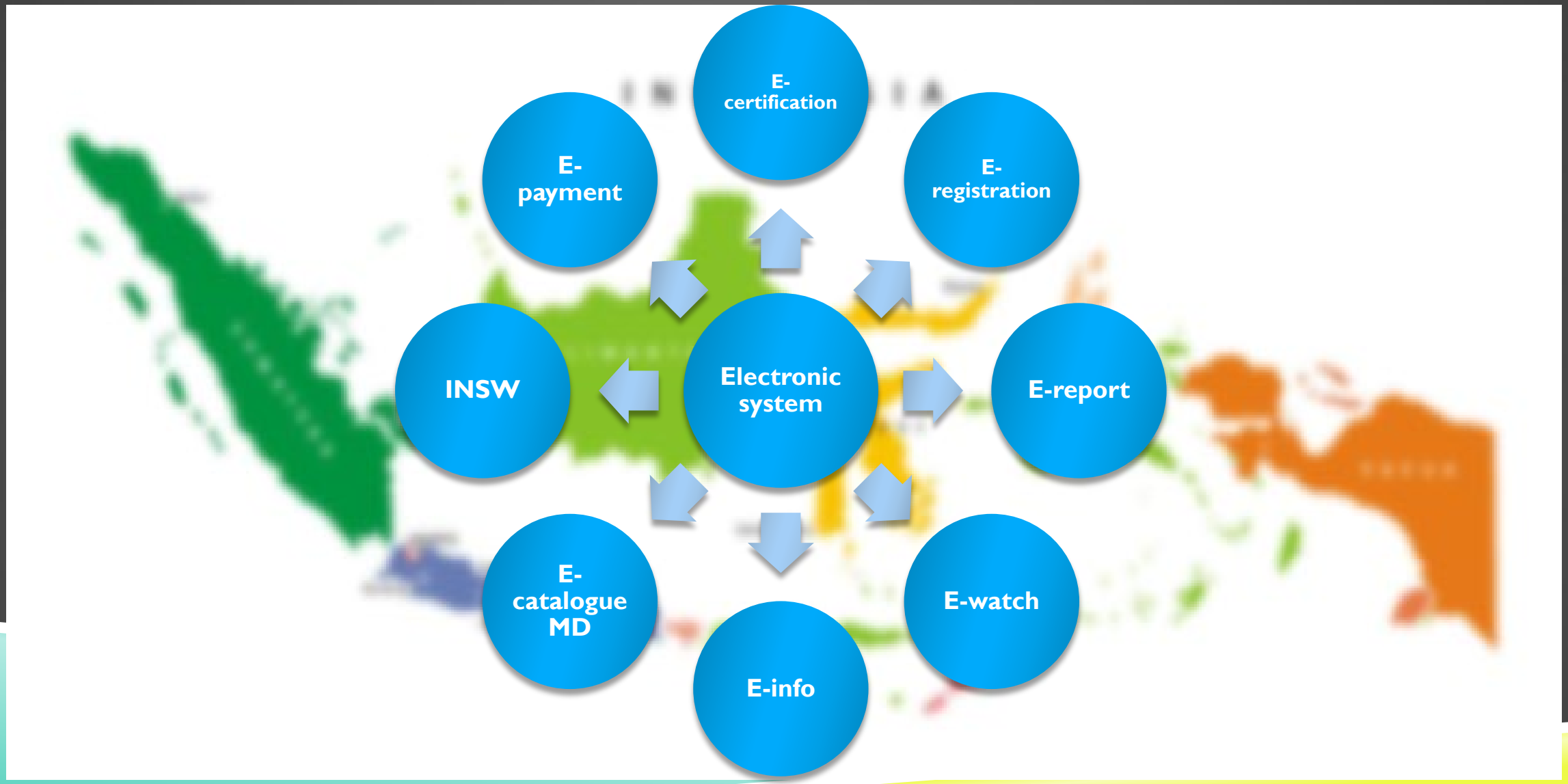
Develop local manufacturer

Deregulation and Debureaucracy Regulation including Medical Device Sector:

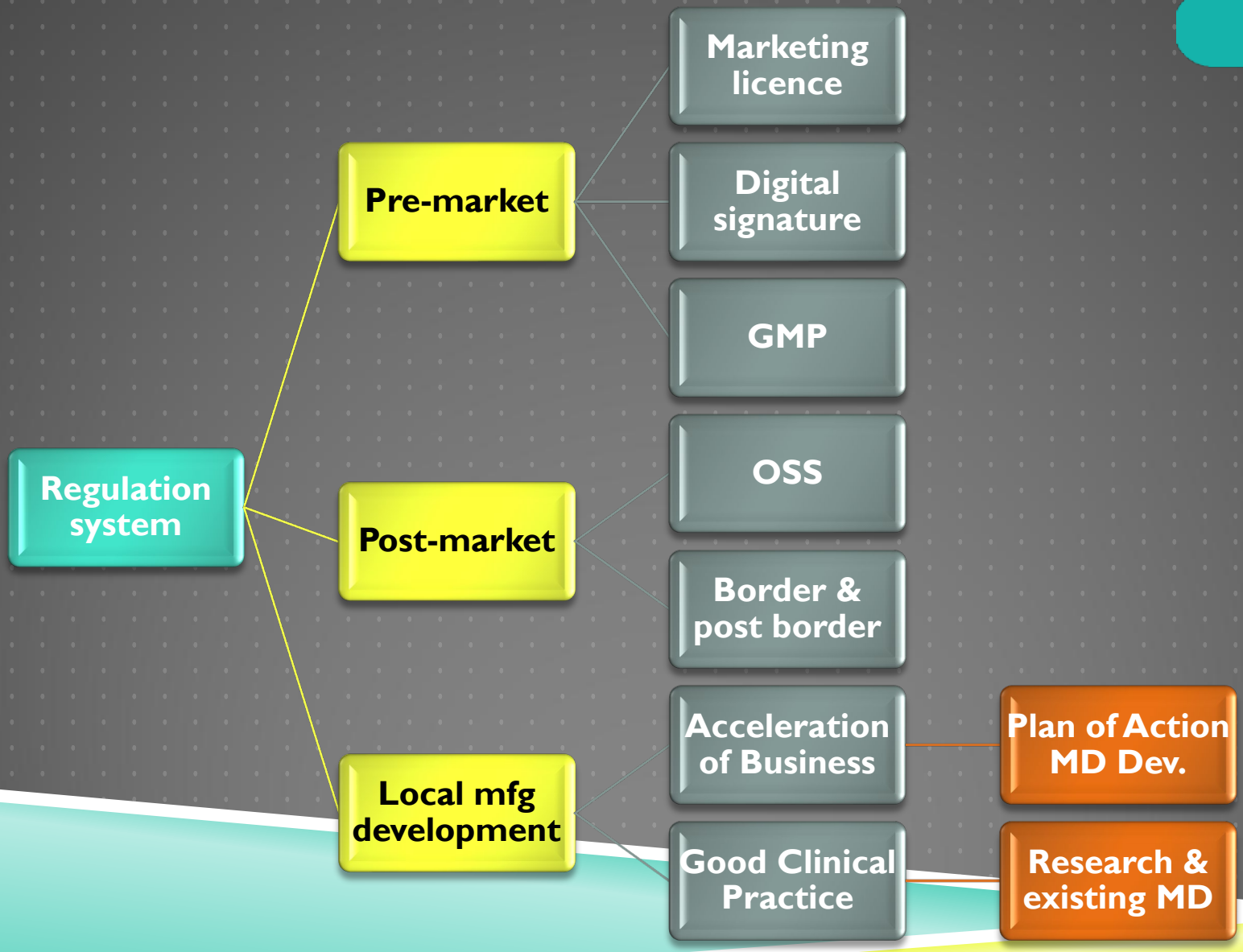
1. Strengthening industrial competitiveness, law enforcement, easiness to invest
2. Accelerate strategic national project
3. Increasing the investment

E-SYSTEM FOR MEDICAL DEVICE

Optimize public service, faster and accessible



REGULATORY UPDATE



REVIEW TIMELINE (DAYS)*

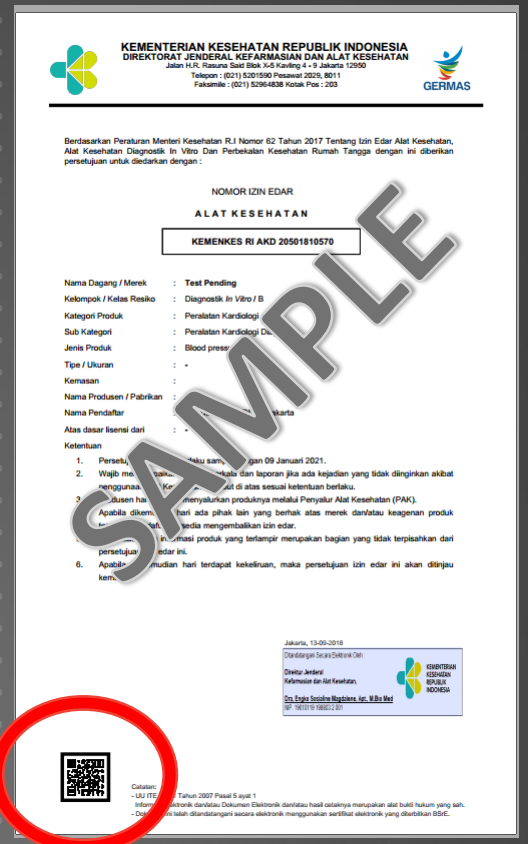
PROCESS	CLASS A	CLASS B	CLASS C	CLASS D
NEW LICENSE	15	30	30	45
RENEWAL	7	7	7	7
VARIATION	10	10	10	10

CLASS	PREVIOUS REGULATION 2010
A	45
B	90
C	90
D	120
Renewal	45
Variation	45

*for completed document at the first submission
Applicant : 10 days for fulfilling lack of document(s), one chance

DIGITAL SIGNATURE

- Indonesia is about to launch Digital signature system on November 2018
- Marketing license approval is signed in the form of electronic formate
- Doesn’t need stamp and direct signature
- Marketing license may be print ed by Applicant and other designated bodies through official website
- Colaborate with State Cyber and Cryptography Agency
- QR Code used for safety and verify-able by Android and IOS application



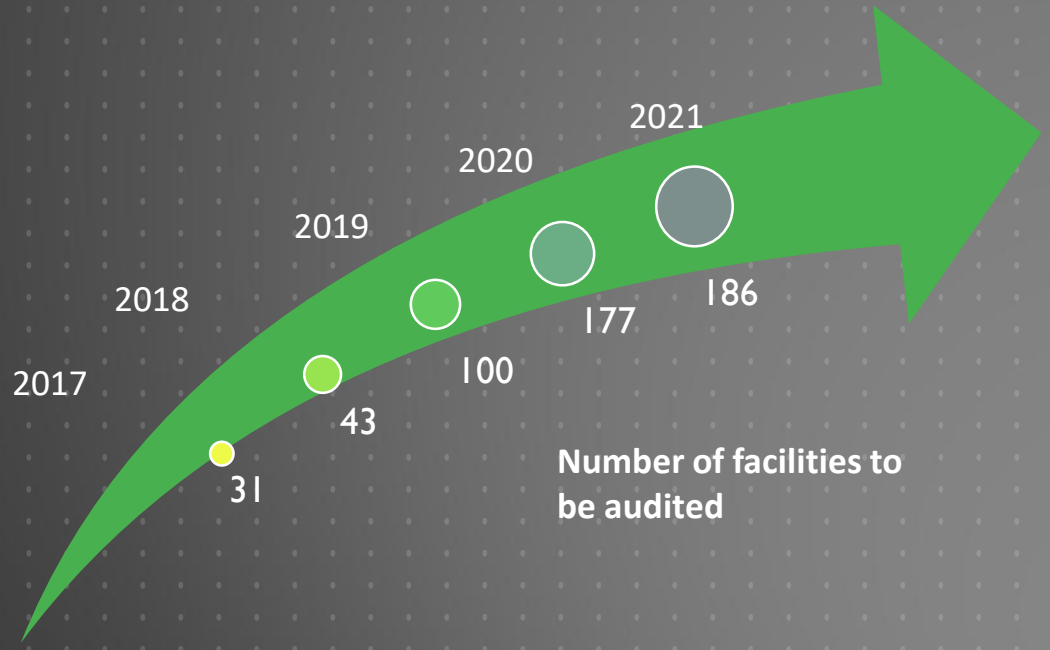
Minister of Health Regulation No. 20 – 2017 Good Manufacturing Practices of Medical Devices

G M P

Mandatory
Good Manufacturing Practice
Medical Device

All Medical device industry must implement Good Manufacturing practice on MD within 4 years at the latest

Roadmap Audit GMP certification 2017 - 2021



10 Potential Industries

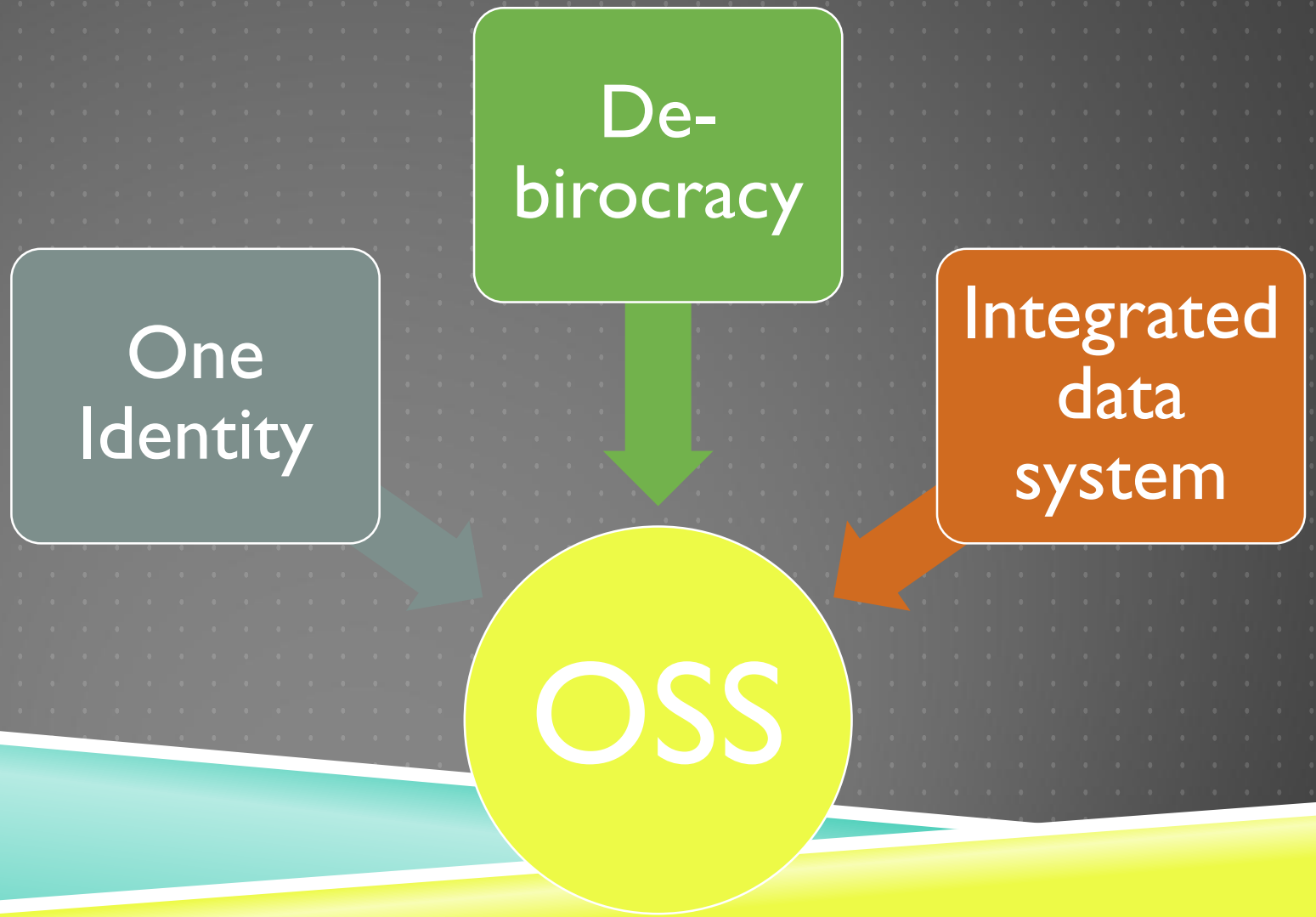
- Contact Lens
- Surgical instrument
- Blood monitor
- Hemodialysis Solution
- Condom
- Rapid test
- Surgical Suture
- Sterilisator
- Orthopedic Implant
- Bandage

OSS *ONLINE SINGLE SUBMISSION*

DEVELOPED BY COORDINATING MINISTRY FOR ECONOMIC AFFAIRS

Government efforts to simplify business licensing and create integrated and fast licensing service models and provide certainty

https://www.oss.go.id/



BORDER DAN POST BORDER

IMPLEMENTATION ON MEDICAL DEVICE IMPORT TRADE CONTROL

Background

- Longer dwelling time, additional cost for warehouse and maintenance

Border control

- 107 HS Codes controled at customs area

Post border control

- 81 HS Codes released, controled outside customs area by MoH
  - OSS Notification system
  - HS Code, Low risk MD

PROGRESS OF ACCELERATION TO DEVELOP PHARMACEUTICAL AND MEDICAL DEVICE INDUSTRY

Economic Policy Package XI

President Instruction No. 6 year 2016

Minister of Health Regulation No 17 year 2017

Presidential Regulation No. 44 Year 2016 regarding list of open and closed business fields (Sector: Medical devices, distribution and production)

No	Business Field in Indonesia territory	Capital ownership
1.	Medical Device Distributor	Foreign capital ownership maks. 49% Special permittance from MOH
2.	Class A MD Manufacturer	Foreign capital ownership maks. 33% Special permittance from MOH
3.	Class B MD Manufacturer	Foreign capital ownership open 100% or may join ventures to local owner Special permittance from MOH
4.	Class C MD Manufacturer	Foreign capital ownership open 100% or may join ventures to local owner Special permittance from MOH
5.	Class D MD Manufacturer	Foreign capital ownership open 100% or may join ventures to local owner Special permittance from MOH

GOOD CLINICAL PRACTICE OF MD

Applied for Risk Class

- C and D medical device

Pre market Clinical Research

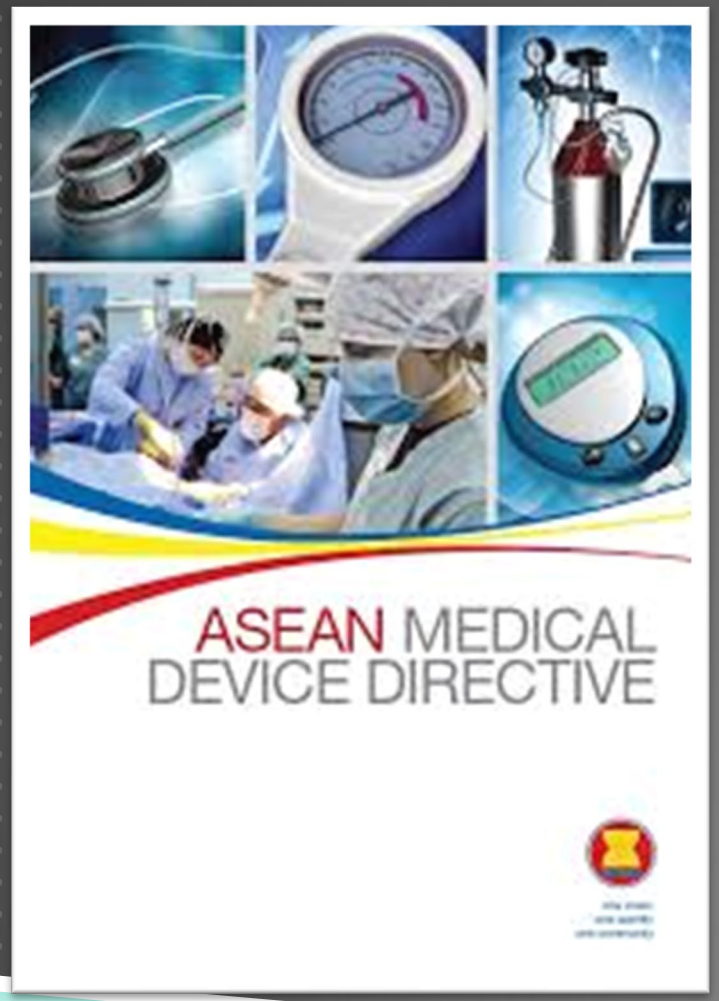
- Sample test does not yet have approval
- Endorsement from Health Minister

New product, New indication or intended use

Post market Clinical Research

- Sample test has marketing license
- Endorsement from Director General

Obtain safety data, performance evidence



ASEAN Medical Device Directives (AMDD) Ratification Progress

- AMDD signed on Nov 2014
- Minister of Health propose the permission initiative to ratify AMDD (Dec 30th 2015)
- Law or President Regulation Preparation is still in domestic Process
- Legislative Approval is needed.

Ratification and the deposit of the instrument of ratification to ASEAN Sec → Fully adoption to National Regulation

THANK YOU

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